

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Notice
of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 24 and 25, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD, 301-652-2000.

Contact Person: Anuja Patel, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, or e-mail: patela@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12543. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 24, 2003, the committee will discuss new drug application (NDA) 21–487, memantine hydrochloride, Forest Laboratories, Inc., indicated for the treatment of moderate to severe dementia of the Alzheimer’s type. On September 25, 2003, the committee will discuss NDA 20–717, Provigil (modafinil) Tablets, Cephalon, Inc., indicated for use to improve wakefulness in patients with excessive sleepiness associated with disorders of sleep and wakefulness.

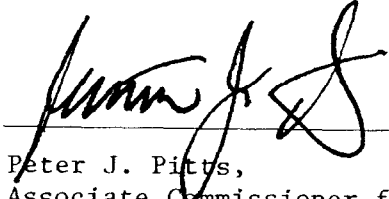
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 15, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 15, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Angie Whitacre at 301–827–7001 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: 7/25/03
July 25, 2003.



Peter J. Pitts,
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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